

Attorney Docket No. 7175-74147

Application No. 10/083,966 (Filed February 25, 2002)

Reply to Office Action dated December 24, 2003

**REMARKS**

Claims 1-8 and 10-47 remain in this application. Claims 1, 10-14, 20, 27 and 34-53 are amended. Claim 9 is canceled. New claims 46 and 47 are added.

Claims 1-45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-55 of U. S. Patent No. 6,379,316. A terminal disclaimer is submitted herewith in compliance with 37 C.F.R. 1.321(c) to overcome the aforesaid double patenting rejection. A check in the amount of \$110.00 to cover the fee for this Terminal Disclaimer is enclosed.

The drawings are objected to under 37 CFR 1.83(a). The Examiner objected to claims 9-11, 14, 17, 21-23, 34-36 and 42 because “the details of the mouthpiece such as the 1.5 inch tongue depressing portion and oval cross section” are not shown. Applicant hereby requests the Examiner’s approval to amend the drawings in the subject application as shown in the attached sheet showing the proposed changes in red ink. Specifically, Fig. 3 is renumbered as Fig. 3a, and the first portion of the mouthpiece 18 which extends about 1.5 inches into the patient’s mouth is shown in phantom. Two new Figs. are added - (i) Fig. 3b showing the circular cross section of the mouthpiece 18 along line 3b-3b in Fig. 3a, and (ii) Fig. 3c showing the oval cross section of the mouthpiece 18 along line 3c-3c in Fig. 3a. The support for the changes can be found for example on page 8 lines 18 et seq. and original claims 21-25. No new matter is introduced by these amendments. Formal drawings containing these changes will be submitted upon the Examiner’s approval.

Reconsideration of the rejection of claims 1, 3-10, 18-20, 27, 40, 41, 44 and 45 under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 4,397,306 to Weisfeldt et al. (“Weisfeldt”) is requested. It is believed that amended independent claims 1, 20 and 27, and dependent claims 3-10, 18, 19, 40, 41, 44 and 45, are not anticipated by Weisfeldt at least for the reasons given below.

Regarding claim 1, Weisfeldt does not disclose or suggest “the first portion of the mouthpiece placed in the patient’s mouth being configured to be spaced apart from the patient’s trachea.” As recited in the specification at page 8, lines 18 et seq., “[m]outhpiece 18 extends about 1.5 inches into mouth M and holds open mouth M while depressing the tongue of the person to maximize airflow velocity.” In contrast, Weisfeldt’s endotracheal tube 12 is placed in the patient’s trachea, and not “spaced apart from the patient’s trachea.” At column 4, lines 13 et

seq., Weisfeldt recites that “[t]he system ventilates the patient's lungs through an endotracheal tube (12) placed in the patient's trachea.” Also, the word “endotracheal” means “placed within the trachea.” *See Merriam Webster's Collegiate Dictionary, Tenth Edition, Merriam-Webster, Inc.* Thus, Weisfeldt clearly intends his endotracheal tube 12 to be placed in the patient's trachea, not “spaced apart from the patient's trachea.”

Regarding claim 20, Weisfeldt does not disclose or suggest in any way, shape or form “the mouthpiece including a port adapted for connection to a source of an aerosolized solution.”

Regarding claim 27, Weisfeldt does not disclose or suggest in any way, shape or form “a mouthpiece having a first opening configured to be received in the patient's mouth, a second opening configured to be positioned outside the patient's mouth and communicating directly with atmosphere and a passageway extending between the first and second openings through which the patient inhales from and exhales to the atmosphere.” Instead, as disclosed at column 4, lines 28 et seq. and shown in Figs. 4 and 5, Weisfeldt's endotrachial tube 12 has one end placed in the patient's trachea and a second end coupled to the lung ventilation means 8 through a set of valves 14-16. Thus, Weisfeldt's tube 12 does not have “a second opening configured to be positioned outside the patient's mouth and communicating with atmosphere.” Also, Weisfeldt's tube 12 does not have “a passageway extending between the first and second openings through which the patient inhales from and exhales to the atmosphere.”

Accordingly, at least for any one of these reasons, applicants respectfully submit that amended independent claims 1, 20 and 27, and dependent claims 3-10, 18, 19, 40, 41, 44 and 45, are not anticipated by Weisfeldt, and hence withdrawal of the above 5 U.S.C. 102(b) rejection thereof is respectfully requested.

Reconsideration of the rejection of claims 12, 13, 18-20, 27, 37, 38, 40, 41 and 43-45 under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 402,779 to Steinhoff (“Steinhoff”) is requested. It is believed that amended independent claims 20 and 27, and dependent claims 12, 13, 18, 19, 37, 38, 41 and 43-45, are not anticipated by Steinhoff at least for the reasons given below.

Claims 12, 13, 18 and depend from amended independent claim 1. Steinhoff does not disclose or suggest in any way, shape or form “a mouthpiece having a first portion configured to extend sufficiently into the patient's mouth to depress the patient's tongue to minimize airflow resistance” as required by claim 1. Instead, Steinhoff discloses an inhalation mouthpiece or mask a', no portion of which extends “into the patient's mouth to depress the patient's tongue.” As clearly disclosed at page 2 lines 20 et seq. and lines 58 et seq. and shown in Fig. 2, Steinhoff's mask a' includes a flap valve b which depends for its operation on breathing of the patient.

Steinhoff's mask a' is clearly not designed to be inserted into the patient's mouth. As shown in Figs. 1 and 2, Steinhoff's mask is not sized and shaped for insertion into the patient's mouth. Also, such action would interfere with the operation of the flap valve b included in the mask a'.

Regarding claim 20, Steinhoff does not disclose or suggest that "the aerosolized solution being fed to the mouthpiece along a path not passing through the vest." Steinhoff, at page 1 lines 53 et seq. recites that "[t]he air, which, if necessary, may be mixed with any medical substances, is forced by any of the known devices - such as pumps ... etc. - into the accumulator." In Steinhoff, the air flows from the accumulator A to the breathing belt C through a valve B and from the breathing belt C to the inhalation mask a' through a valve D. See page 1 lines 60 et seq. and lines 97 et seq. and shown in Fig. 1. Thus, Steinhoff does not disclose or suggest any path not passing through his breathing belt for feeding "the aerosolized solution ... to the mouthpiece."

Regarding claim 27, Steinhoff does not disclose or suggest "a mouthpiece having a first opening configured to be received in the patient's mouth, a second opening configured to be positioned outside the patient's mouth and communicating directly with atmosphere." Instead, Steinhoff discloses an inhalation mask a' which is held by the patient against his mouth and has a distal end connected to the breathing belt C by a tube *a* through a valve D. The distal end of Steinhoff's mask is not "configured to be positioned outside the patient's mouth and communicating directly with atmosphere." Also, Steinhoff does not disclose or suggest "a mouthpiece having ... a passageway extending between the first and second openings through which the patient inhales from and exhales to the atmosphere." Instead, as disclosed at page 2 lines 8 et seq. and lines 58 et seq., Steinhoff teaches an inhalation mask a' through which the patient *only* inhales the compressed air from the breathing belt C, but the patient exhales through his nose, and not through the inhalation mask a'.

Accordingly, at least for any one of these reasons, applicants respectfully submit that amended independent claims 20 and 27, and dependent claims 12, 13, 18, 19, 37, 38, 41 and 43-45, are not anticipated by Steinhoff, and hence withdrawal of the above 5 U.S.C. 102(b) rejection thereof is respectfully requested.

Reconsideration of the rejection of claims 27, 29-33, 40, 41 and 43-45 under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 4,977,889 to Budd ("Budd") is requested. It is believed that amended independent claim 27, and dependent claims 29-33, 40, 41 and 43-45, are not anticipated by Budd at least for the reasons given below.

Regarding claim 27, Budd does not disclose or suggest "a mouthpiece having a first opening configured to be received in the patient's mouth, a second opening configured to be positioned outside the patient's mouth and communicating directly with atmosphere and a

passageway extending between the first and second openings through which the patient inhales from and exhales to the atmosphere.” Instead, as disclosed at column 3 lines 26 et seq. and shown in Fig. 1, Budd’s conduit 110 has a proximal end placed in patient’s mouth and a distal end coupled to a fluid measuring device 108. The conduit 110 does not have “a second opening configured to be positioned outside the patient’s mouth and communicating directly with atmosphere.”

Accordingly, at least for any one of these reasons, applicants respectfully submit that amended independent claim 27, and dependent claims 29-33, 40, 41 and 43-45, are not anticipated by Budd, and hence withdrawal of the above 5 U.S.C. 102(b) rejection thereof is respectfully requested.

Reconsideration of the rejection of claims 11 and 15-18 as being unpatentable under 35 U.S.C. 103(a) over Weisfeldt is requested. Claims 11 and 15-18 depend from claim 1, and are therefore patentably distinguishable over Weisfeldt for the reasons given above in support of claim 1. Specifically, Weisfeldt does not disclose or suggest “the first portion of the mouthpiece placed in the patient’s mouth being configured to be spaced apart from the patient’s trachea.” Accordingly, at least for any one of these reasons, applicants respectfully submit that claims 11 and 15-18 patentably distinguish over Weisfeldt, and hence withdrawal of the above 5 U.S.C. 103(a) rejection thereof is respectfully requested.

Reconsideration of the rejection of claims 14, 20-26, 34-36, 39 and 42 as being unpatentable under 35 U.S.C. 103(a) over Steinhoff in view of U.S. Pat. No. 5,398,676 to Press et al. (“Press”) is requested.

Claim 14 depends from claim 1, and is therefore patentably distinguishable over Steinhoff for the reasons given above in support of claim 1. Specifically, Steinhoff does not disclose or suggest in any way, shape or form “a mouthpiece having a first portion configured to extend sufficiently into the patient’s mouth to depress the patient’s tongue to minimize airflow resistance,” nor to have the “second portion... directly communicating with atmosphere.” Press is neither proffered for nor does it overcome the foregoing deficiency of Steinhoff. Thus, Press does not disclose or suggest in any way, shape or form “a mouthpiece having a first portion configured to extend sufficiently into the patient’s mouth to depress the patient’s tongue to minimize airflow resistance” and to have the “second portion...directly communicating with the atmosphere.”

Claims 21-26 depend from claim 20, and are therefore patentably distinguishable over Steinhoff for the reasons given above in support of claim 20. Specifically, Steinhoff does not disclose or suggest that “the aerosolized solution being fed to the mouthpiece along a path not passing through the vest.” Press is neither proffered for nor does it overcome the foregoing

deficiency of Steinhoff. Thus, Press does not disclose or suggest in any way, shape or form “the aerosolized solution being fed to the mouthpiece along a path not passing through the vest.”

Claims 34-36, 39 and 42 depend from claim 27, and are therefore patentably distinguishable over Steinhoff for the reasons given above in support of claim 27. Specifically, Steinhoff does not disclose or suggest “a mouthpiece having a first opening configured to be received in the patient’s mouth, a second opening configured to be positioned outside the patient’s mouth and communicating directly with atmosphere.” Press is neither proffered for nor does it overcome the foregoing deficiencies of Steinhoff. Thus, Press does not disclose or suggest in any way, shape or form “a mouthpiece having a first opening configured to be received in the patient’s mouth, a second opening configured to be positioned outside the patient’s mouth and communicating directly with atmosphere.”

Accordingly, at least for any one of these reasons, applicants respectfully submit that claims 14, 20-26, 34-36, 39 and 42 patentably distinguish over Steinhoff in view of Press, and hence withdrawal of the above 5 U.S.C. 103(a) rejection thereof is respectfully requested.

New claim 46 is believed to be allowable because none of the cited art teach or fairly suggest the limitation “a mouthpiece having a first opening configured to be received in the patient’s mouth, a second opening configured to be positioned outside the patient’s mouth and communicating directly with atmosphere and a passageway extending between the first and second openings through which the patient inhales from and exhales to the atmosphere.” New claim 47 depends from claim 46, and is therefore believed to be allowable.

Claims 1-47 are now in condition for allowance and such action is respectfully requested. If the Examiner believes that a telephonic interview would expedite the allowance of this application, he is requested to contact the undersigned for a prompt resolution of any outstanding issues.

Examiner DeMille is thanked for the courtesy extended during the recent interview where the above amendments and comments were discussed. The Examiner’s Summary of the interview appears to be a complete and correct summary of the interview.

It is respectfully requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time sufficient to effect a timely response and shortages and other fees be charged, or any overpayment in fees be credited, to the Account of Barnes & Thornburg, Deposit Account No. 10-0435, with reference to file 7175-71147. A duplicate copy of this authorization is enclosed.

Respectfully submitted,

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